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10/690,772	10/22/2003	Christopher M. Kim	CKIM 3.0-001 DIV	6954

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,772	KIM, CHRISTOPHER M.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 04/18/2007 is acknowledged.

2. Claims 1-18 are pending.

3. Claims 1-18 are under examination as they read on a pharmaceutical compound comprising a therapeutically effective amount of bee venom and an anesthetic.

Claim Objections

4. Claim 15 is objected to because of the following informalities:

Claim 15 recites '9,500 mg of total protein', but it should recite '9,500 **mcg** of total protein.' Appropriate correction is required.

5. In view of the amendment filed on 04/18/2007, only the following rejections are maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9 and 11-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwaldt et al. (Reference CD on the IDS filed 10/22/2003, entire document) as evidenced by the specification at Table 1 on page 8 for the same reasons as set forth in the Office Action mailed on 01/04/2007.

Applicant's arguments filed on 04/18/2007 have been fully considered, but are not found persuasive.

Applicant argues that claim amendments including the limitation of filtering the bee venom through a 25 mcm or less filter will obviate the rejection since Steigerwaldt et al. does not teach such filtration. The Examiner rejected Claim 11 because standardized bee venom preparation produced by filtering adds no patentable weight since the been venom preparation of Steigerwaldt et al. is for in vivo use and is inherently sterilized and purified for pharmaceutical use. Applicant argues that for the Examiner to argue inherency the prior art bee venom preparation must necessarily be the same as the claimed preparation. Applicant further argues that even if the bee venom of Steigerwaldt et al. is sterilized and purified for pharmaceutical use, such a bee venom preparation is inherently as pure as that produced in the present invention. Applicant argues that "the examiner fails to provide objective evidence or cogent technical reasoning to support the conclusion of inherency."

The Examiner maintains that the recitation of filtering the bee venom through a 25 mcm or less filter adds no patentable weight for many reasons. First, the Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced bee venom preparation for pharmaceutical *in vivo* use. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997). Second, and most importantly, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113. Therefore, the limitations of "purified by a method comprising filtering through a 25 mcm or less filter" of claim 1; "being filtered through a 25 mcm or less filter of claim 11; "wherein said bee venom is purified by a method comprising filtering through a 25 mcm or less filter" of claim 13; and wherein said bee venom is collected using a low voltage electric shock method and air dried under a temperature of about 4°C" of claim 14 lend no patentable weight to the claims. Third, applicant has claimed a pharmaceutical composition **comprising** bee venom and an anesthetic. The open language of the claim allows for the addition of other components, including the impurities that applicant seeks to filter out through the newly added claim limitations.

Newly added claim 13 is included in this rejection because the limitation of filtering through a 25 mcm or less filter adds no patentable weight for the same reasons as stated *supra*.

Newly added claim 14 is included in this rejection because the limitation of wherein said bee venom is collected using low voltage electric shock method and air dried under a temperature of about 4°C adds no patentable weight.

Newly added claim 15 is included in this rejection the limitation of wherein the standard bee venom comprises about .01 to about 1.0 mg or melittin and about 80 to about 9,500 **mcg** of total protein per ml is taught by Steigerwaldt et al. where .06 mg to 1.62 mg of bee venom were injected in .1 cc (In particular, page 1047, right column). It is noted that the Examiner believes a typographical error was made in Claim 15 in the recitation of 9,500 **mg** of total protein, so the art is being applied as though it is 9,500 mcg, not 9,500 mg. The specification at Table 1 on page 8 discloses that <6.51-7.51 % of bee venom is non-peptide components. Therefore, 93.49-92.49 % of bee venom is protein. Table 1 also shows that 40-50% of bee venom is melittin. Therefore, Steigerwaldt teaches injection of .24 to 8.1 mg of melittin and .55494 to 15.1453 mg of protein per ml, which is about .01 to 1.0 mg of melittin and about 80 to 9,500 mcg of total protein per ml.

Newly added claim 16 is included in this rejection the limitation of wherein the standard bee venom comprises about .01 to about .10 mg or melittin and about 400 to about 4,500 mcg of

total protein per ml is taught by Steigerwaldt et al. where .06 mg to 1.62 mg of bee venom were injected in .1 cc (In particular, page 1047, right column). The specification at Table 1 on page 8 discloses that <6.51-7.51 % of bee venom is non-peptide components. Therefore, 93.49-92.49 % of bee venom is protein. Table 1 also shows that 40-50% of bee venom is melittin. Therefore, Steigerwaldt teaches injection of .24 to 8.1 mg of melittin and .55494 to 15.1453 mg of protein per ml, which is about .01 to .10 mg of melittin and about 400 to 4,500 mcg of total protein per ml.

Newly added claim 17 is included in this rejection the limitation of wherein the standard bee venom comprises about .01 to about 1.0 mg or melittin and about 800 to about 950 mcg of total protein per ml is taught by Steigerwaldt et al. where .06 mg to 1.62 mg of bee venom were injected in .1 cc (In particular, page 1047, right column). The specification at Table 1 on page 8 discloses that <6.51-7.51 % of bee venom is non-peptide components. Therefore, 93.49-92.49 % of bee venom is protein. Table 1 also shows that 40-50% of bee venom is melittin. Therefore, Steigerwaldt teaches injection of .24 to 8.1 mg of melittin and .55494 to 15.1453 mg of protein per ml, which is about .04 to .05 mg of melittin and about 800 to 950 mcg of total protein per ml.

Newly added claim 18 is included in this rejection because the recitation of a bee venom preparation which exhibits 40 to 100 HHU/ml does not add any patentable weight since it is an arbitrary term that is not defined in the specification or prior art.

The prior art teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwaldt et al. (IDS filed on 10/23/2003; entire document), in view of Simics (PTO-892; Reference U, In particular, entire document) for the same reasons as set forth in the Office Action mailed on 01/04/2007.

Applicant's arguments filed on 04/18/2007 have been fully considered, but are not found persuasive.

Applicant argues that Steigerwaldt et al. fails to provide a person skilled in the art any suggestion or motivation to provide bee venom that has a purity such as that which could be achieved by filtering through a 25 mcm or less filter. Applicant acknowledges that Simics et al. teaches using bee venom with lidocaine, but applicant argues that there is no motivation to use the claimed filtered venom.

As stated above, the Examiner maintains that the recitation of filtering the bee venom through a 25 mcm or less filter adds no patentable weight for many reasons. First, the Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced bee venom preparation for pharmaceutical *in vivo* use. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997). Second, and most importantly, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113. Therefore, the limitations of "purified by a method comprising filtering through a 25 mcm or less filter" of claim 1; "being filtered through a 25 mcm or less filter of claim 11; "wherein said bee venom is purified by a method comprising filtering through a 25 mcm or less filter" of claim 13; and wherein said bee venom is collected using a low voltage electric shock method and air dried under a temperature of about 4°C" of claim 14 lend no patentable weight to the claims. Third, applicant has claimed a pharmaceutical composition **comprising** bee venom and an anesthetic. The open language of the claim allows for the addition of other components, including the impurities that applicant seeks to filter out through the newly added claim limitations.

10. The following new grounds of rejection are necessitated by the amendment filed on 04/18/2007.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of 'wherein the standard bee venom preparation exhibits 40 to 100 HHU/ml of hyaluronidase activity' is indefinite because the specification does not disclose, nor does the prior art teach the definition of an 'HHU.'

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-10 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "pharmaceutical composition" claimed in claims 1-10 and 13-14; and "a 25 mcm or less filter" in claims 1, 11, 13 and 15; "9,500 mg" of claim 15 represents a departure from the specification and the claims as originally filed.

Applicant's amendment filed 04/18/2007 points to the specification at page 4, paragraph [0010], page 10 at paragraphs [0023] and [0024], page 11 at paragraph [0026], and page 13 paragraphs [0031] and [0032] for the newly added limitations. However, the specification does not provide a clear support of "pharmaceutical composition"; "a 25 mcm or less filter"; or "9,500 mg." The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 2, 2007
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Maher M. Haddad
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PRIMARY EXAMINER